

REMARKS

The present application was filed on March 27, 2001 (claiming priority from United States Provisional Application Number 60/245,396, filed November 2, 2000) with claims 1-43. Claims 7-21, 28-32 and 39-43 have been withdrawn from consideration in response to a restriction requirement and claims 4, 25 and 36 have been withdrawn from consideration in response to a species election. Therefore, claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 are presented herein for examination on the merits. Applicant acknowledges that while claims 4, 7-21, 25, 28-32, 36 and 39-43 have been withdrawn from consideration, as highlighted above, these claims are still pending in the present application.

In the outstanding Office Action, the Examiner finally rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner found that the limitation of determining a hydrophobicity distribution of a protein, e.g., as recited in claims 1, 22 and 33, to be vague and indefinite.

The Examiner further finally rejected claims 1-3, 5 and 6 under 35 U.S.C. §101 as allegedly drawn to non-statutory subject matter. Specifically, the Examiner maintained that the present teachings are drawn to a non-tangible mathematical invention.

The Examiner finally rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Specifically, the Examiner maintained that the present specification does not provide enablement for a method of profiling proteins by physically changing the protein's hydrophobicity in a real environment.

The Examiner finally rejected claim 1 under 35 U.S.C. §102(b) as allegedly unpatentable over Bar-Or et al., Database CaPlus, DN 103:84898, Archives of Microbiology (1985), 142(1), pages 21-27 (hereinafter "Bar-Or").

The present invention has been described in Applicant's prior response, incorporated by reference herein.

FORMAL REJECTIONS

As mentioned above, the Examiner finally rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner found the limitation present in each of claims 1, 22 and 33 directed to determining a hydrophobicity distribution of a protein to be vague and indefinite. Namely, the Examiner submitted that the specification “may explain the term hydrophobicity distribution of amino acid residues in [a] protein, but not the hydrophobicity distribution of a protein as used in the claims.” See final Office Action, page 3, 1<sup>st</sup> paragraph (internal punctuation omitted).

Applicant respectfully submits that the specification clearly supports determining a hydrophobicity distribution of a protein, such that one of ordinary skill in the art would understand the concept and scope of this limitation. By way of example only, the specification at page 4, lines 24-25, recites that a hydrophobicity scale can be used to determine the hydrophobicity distribution of a protein. An exemplary hydrophobicity scale, such as that shown, for example, in FIG. 2, can be used to assign individual hydrophobicities for each residue of a protein. Thus, in this exemplary embodiment, the hydrophobicity distribution arises from the spatial distribution of the residues and their assigned values of hydrophobicity. See, for example, page 9, lines 1-5 of the specification and FIG. 2. Therefore, the specification clearly supports and defines the scope of determining the hydrophobicity distribution of a protein.

As such, one of ordinary skill in the art would be able to ascertain the metes and bounds of the present claims from the teachings of the specification. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection.

As further mentioned above, the Examiner finally rejected claims 1-3, 5 and 6 under 35 U.S.C. §101 as allegedly drawn to non-statutory subject matter. The Examiner maintained that “the listed instant claims are drawn to computation or manipulation of data or abstract information. . . . No production or change in actual material is seen in the instant claims and thus it is deemed non-statutory subject matter.” See, final Office Action, page 3, 2<sup>nd</sup> paragraph.

Applicant respectfully disagrees with the Examiner's assertions. Independent claim 1, from which claims 2, 3, 5 and 6 ultimately depend, is expressly directed to a practical method for "spatially profiling proteins." Thus, these claims are clearly tied to a practical application. A process that is limited to a practical application of an abstract idea or mathematical algorithm in the technological arts is patentable. See Examination Guidelines for Computer-Related Inventions, § IV. B. 2. b. (ii). In any event, the analysis does not stop there. The Supreme Court has stated that the "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to patentability of a process claim." *Gottshalk v. Benson*, 409 U.S. 63, 70, 175 U.S.P.Q. (BNA) 676 (1972). In other words, claims that require some kind of transformation of subject matter, which has been held to include intangible subject matter, such as data or signals, that are representative of or constitute physical activity or objects have been held to comply with § 101. See, for example, *In re Warmerdam*, 31 U.S.P.Q.2d (BNA) 1754, 1759 n.5 (Fed. Cir. 1994) or *In re Schrader*, 22 F.3d 290, 295, 30 U.S.P.Q.2d (BNA) 1455, 1459 n.12 (Fed. Cir. 1994). Thus, as expressly set forth in independent claim 1, a hydrophobicity distribution of a protein is determined. The hydrophobicity distribution is then *transformed* by being shifted.

Further, the present Action makes no mention of Applicant's prior response wherein it was pointed out that the hydrophobicity distribution which has been shifted is a useful, concrete and tangible result that is produced. Applicant respectfully maintains that assertion and, in further support of this point, additionally submits that without this shifting of the hydrophobicity distribution, the ability to compare different proteins would be significantly degraded. See, for example, page 5, lines 1-2 of the specification.

Therefore, in view of the foregoing arguments, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-3, 5 and 6 under 35 U.S.C. §101.

As mentioned above, the Examiner also finally rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Specifically, the Examiner maintains the assertion that, while being enabling for a computer-driven computational method in a virtual environment, the specification does not reasonably provide enablement for a method of profiling proteins by physically changing the protein's

hydrophobicity in a real environment. The Examiner further indicates that Applicant's previous response indicates that the claims encompass not only computer-generated shifting in hydrophobicity but also physical processes. Respectfully, Applicant disagrees with the Examiner's assertions especially those which appear to mischaracterize Applicant's previous response.

In the previous response, Applicant pointed out that the overall teachings of the specification and claims do not teach or suggest, e.g., physically changing or shifting the hydrophobicity distribution of a protein in a real environment, and such a hypothetical scenario, given the teachings of the present invention, would not be apparent to one of ordinary skill in the art.

Applicants have highlighted that M.P.E.P. §2164.08 indicates that "when analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification." (emphasis added) To assert that certain hypothetical embodiments are not enabled by the specification ignores the overall teachings of the specification and claims which do not teach or suggest, e.g., physically shifting the hydrophobicity distribution of a protein. Further, one of ordinary skill in the art would not contemplate such derivations of the present teachings, as it is not apparent, if at all possible, how one might go about physically shifting the hydrophobicity distribution of a protein. Thus, Applicant respectfully maintains that the present specification clearly enables the scope of the claims to which Applicant is entitled.

#### PRIOR ART REJECTIONS

The Examiner has finally rejected claim 1 under 35 U.S.C. §102(b) as allegedly unpatentable over Bar-Or. Applicant respectfully traverses the Examiner's rejection on the basis that Bar-Or does not teach or suggest either 1) determining a hydrophobicity distribution of a protein or 2) shifting the hydrophobicity distribution, both limitations present in independent claim 1.

Bar-Or is directed to experimentally shifting cell-surface hydrophobicity to hydrophilicity. See, for example, Bar-Or, Abstract. Bar-Or does not teach or suggest

determining a hydrophobicity distribution of a protein. Simply put, Bar-Or makes no mention of the hydrophobicity of any given protein. The techniques mentioned in Bar-Or are directed to shifting cell surface hydrophobicity. The distribution of hydrophobicity in a protein is not taught in Bar-Or.

5 Further, Bar-Or does not teach or suggest shifting the hydrophobicity distribution. What Bar-Or teaches is shifting cell surface hydrophobicity to hydrophilicity by “releasing large amounts of protein . . . from the cell wall.” Bar-Or, Abstract. This teaching is not at all related to shifting the hydrophobicity distribution of a protein. Bar-Or simply does not teach or suggest protein profiling techniques.

10 As such, Bar-Or does not teach or suggest either determining a hydrophobicity distribution of a protein or shifting the hydrophobicity distribution. Therefore, Applicant respectfully requests withdrawal of the rejection.

In view of the foregoing, the invention, as claimed in claim 1, cannot be said to be taught or suggested by Bar-Or. Accordingly, Applicant submits that all claims presented here for  
15 examination, i.e., claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38, are in condition for allowance and such favorable action is earnestly solicited.

If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number indicated below.

20 The Examiner’s attention to this matter is appreciated.

Respectfully submitted,



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